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## Working with Human Subjects: Data Access, Use, Storage, & Sharing

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# **Working with Human Subjects:** Data Access, Use, Storage, & Sharing

Presented by:  
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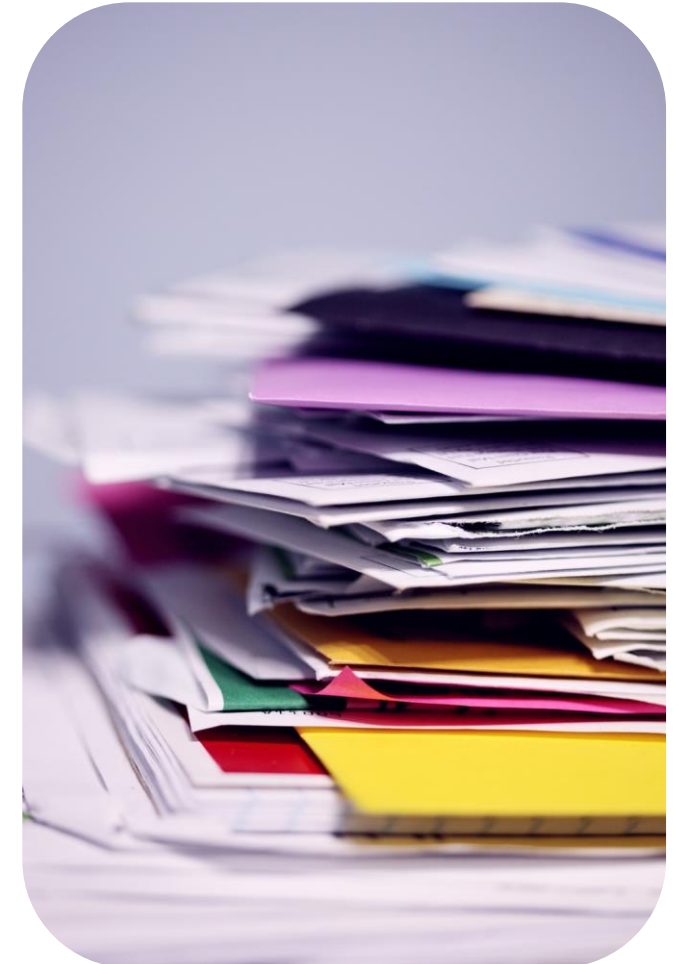
# Researchers must protect the rights, welfare, and safety of human research subjects.

**Research:** systematic investigation that develops *generalizable* knowledge

**Human Subjects:** living individuals targeted by an investigator for conducting research by obtaining data through:

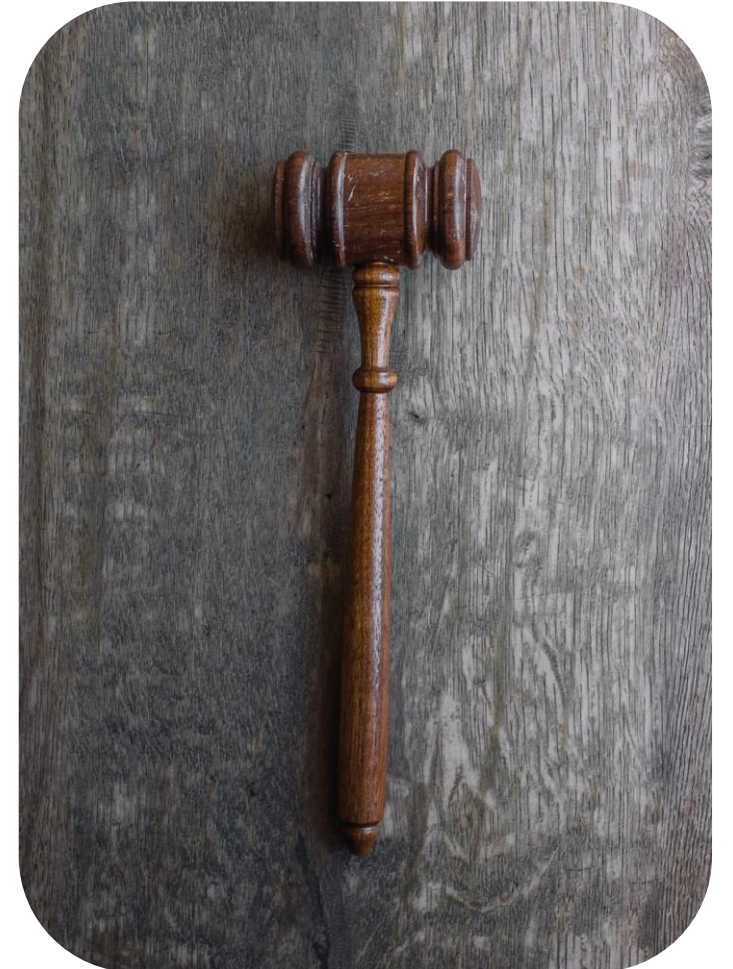
- intervention or interaction with the person
- identifiable personal information

Risk: probability and magnitude of harm or injury



# ERAU's Institutional Review Board reviews research involving human subjects.

- Federally mandated under the Department of Health & Human Services
- Reports to ERAU's Legal Department
- Committee of faculty, staff, and non-ERAU community members
- University Policy on Human Subject Research ([APPM 12.2](#))



# IRB protocol deviations are serious and can impact funding available to the institution.

Minor Deviation: does not harm or potentially harm the participants

- E.g. Minor change in survey wording
- Report to IRB when discovered
- Protocol modification paperwork may be required; data *may* be salvaged

Major Deviation: harms or potentially harms participants

- E.g. failure to consistently collect informed consent
- E.g. failure to follow participant selection criteria
- Report to IRB
- Data likely to be discarded



[https://kpbs.media.clients.ellingtoncms.com/img/photos/2019/04/17/zhang-square\\_1600.jpg?4326734cdb8e39baa3579048ef63ad7b451e7676](https://kpbs.media.clients.ellingtoncms.com/img/photos/2019/04/17/zhang-square_1600.jpg?4326734cdb8e39baa3579048ef63ad7b451e7676)

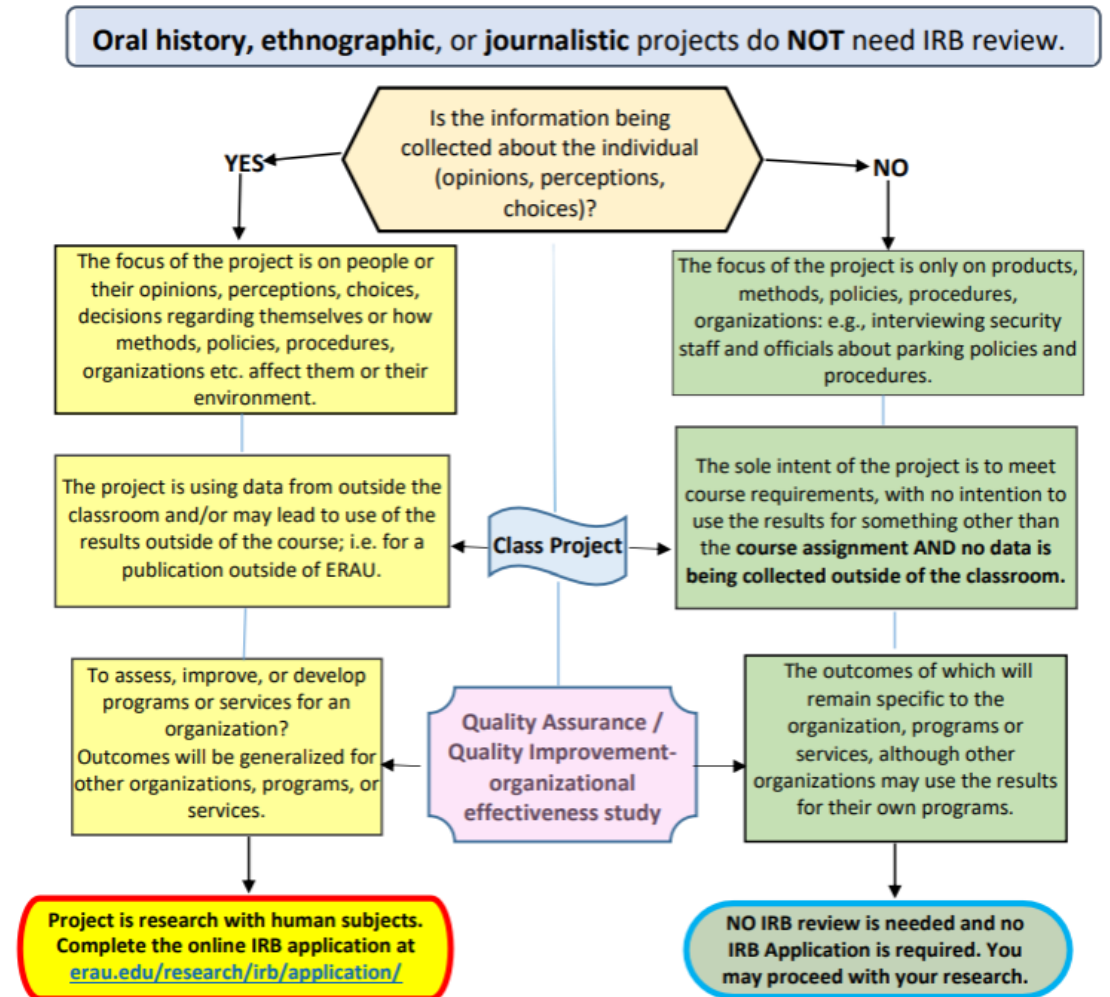


# Use the Decision Tree to determine if your project needs IRB review.

Decision Tree 1: Collecting new data

Decision Tree 2: Using existing data

If your project needs IRB review, review the application process.



# If you do need IRB review, you must complete the mandatory training.

- [CITI Training](#) - Collaborative Institutional Training Initiative
- Recertification every 3 years
- Required for anyone who:
  - collects or enters raw data
  - conducts study procedures
  - has access to private information that can be linked to research subjects



# One IRB decision is “exempt”.

- **Educational research** (instructional strategies, classroom management, or curricula)
  - Commonly accepted educational setting
  - Normal educational practices
- **Educational research** using tests, surveys, interviews, or observation (including recording)
- Research involving **benign behavioral interventions** (brief and harmless) if the participant prospectively agrees to the intervention
- **Secondary research** using identifiable private information or identifiable biospecimens for which consent is not required (e.g. publicly available or anonymous information)
- **Research** conducted/supported by a Federal agency, designed to study, evaluate, improve, or otherwise examine public benefit or service programs.



# Another IRB decision is “expedited review”.

- Non-exempt research that poses no more than minimal risk to participants
- Minor changes in previously approved research
- Research for which **Limited IRB review** is a condition of *exemption*.
  - **Storage or maintenance** of identifiable private information or identifiable biospecimens for which broad consent is required for **potential secondary research use**
  - **Use** of identifiable private information or identifiable biospecimens for **secondary research use**

# For projects with greater than minimal risk, there is a full IRB review.

- fully convened IRB meeting
- 1 – 3 months for decision



# Test Your Knowledge

You tried a new strategy in your class to great success!

Now you want to collect the data you already have and use it to show effectiveness of the strategy.

- Exam grades
- Time on task for the exams (logged by Canvas)

Do you need IRB approval?

# Test Your Knowledge

You are aiming for a competitive grant program and know that preliminary data will bolster your proposal.

You collect preliminary data regarding a subset of students for use in the grant, but with no intent to publish the data.

Do you need IRB approval?

As educators, we have access to a large number of potential participants: our students!

**Position of authority may compromise voluntary participation**

There must be fairness in selecting participants (benefits and risks)



# Plan ahead for your IRB proposal.

## How will you ...

- minimize **risks** and potential for **harm**?
- recruit participants?
- collect and manage [informed consent](#)?
- address **privacy**: anonymity or confidentiality?
- address risks, stresses, discomforts to participants?
- protect vulnerable populations?
- decide what sensitive information is necessary?
- evaluate whether risks are reasonable compared to benefits?
- use and store the data?





# You may offer incentives for participation.

- IRB permits modest academic credit for encouraging participation in research
  - Must offer opportunity to achieve this credit to non-participants based on a comparable commitment of effort
- Anonymity protects against potential for coercion
  - Eliminates most (if not all) incentives for participation
  - Can use technological buffer to maintain anonymity for some incentives



# Once you get IRB approval, you can proceed with recruitment and data collection

- Collect informed consent if your research is not exempt
- Follow your proposal:
  - privacy (people and setting)
  - confidentiality (data management)
    - Collect approved identifying data
    - Code data
      - Limit access to master code list
      - Store in separate location
    - Restrict access
      - Encryption
      - Locked access
      - Virus and intruder protection



# You must follow your plan for protecting confidentiality when storing data.

- Store identifying information separate from other data
- Restrict access to data and master code list (if coded)
- Encrypted identifiable data
- Limit use of cloud-based storage
- Data destruction



# Test Your Knowledge

After attending a conference, you decide to apply a new teaching strategy in your course. However, it takes a *lot* of time to implement the strategy so you decide to start with just one module and see what students think. You gather feedback from students through a survey so you can decide if you want to invest your time in redeveloping the entire course.

Do you need IRB approval?

# Test Your Knowledge

After implementing one changed module, you notice that student retention of information from that module on the final exam seems to be higher.


You want to present the results at a conference.

Do you need IRB approval?

# In Summary ...

- ✓ ERAU has an Institutional Review Board to oversee research involving human subjects
- ✓ You must be trained to perform research with Human Subjects
- ✓ IRB proposals are deemed “exempt”, “expedited”, or “full review”, depending upon the risks and participants.
- ✓ Carefully consider
  - Risks
  - Privacy
  - Informed Consent
- ✓ Survey incentives may complicate privacy





Thank You

*Any Questions?*

[https://www.surveymonkey.com/r/ERAU\\_IRB](https://www.surveymonkey.com/r/ERAU_IRB)